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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ASTRAZENECA AB, ASTRAZENECA LP, KBI-E INC., and POZEN, Inc.

Plaintiffs

v.

WATSON LABORATORIES, INC. – FLORIDA and ACTAVIS PHARMA, INC.,

Defendants.

Civil Action No.

COMPLAINT FOR PATENT INFRINGEMENT AND CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.

COMPLAINT FOR PATENT INFRINGEMENT

AstraZeneca AB, AstraZeneca LP, and KBI-E Inc. and Pozen, Inc. (collectively, "Plaintiffs") for their Complaint against Watson Laboratories, Inc. – Florida and Actavis Pharma, Inc. (collectively, "Defendants"), hereby allege as follows:

THE PARTIES

1. Plaintiff AstraZeneca AB is a company organized and existing under the laws of Sweden, having its principal place of business at Södertälje, Sweden. AstraZeneca AB was a corporate name change from Astra Aktiebolaget.

2. Plaintiff AstraZeneca LP is a limited partnership organized under the laws of Delaware, having its principal place of business at Wilmington, Delaware. AstraZeneca LP holds approved New Drug Application No. 022511 from the United States Food and Drug Administration ("FDA") for a delayed-release naproxen / esomeprazole magnesium formulation that it sells under the name VIMOVO®.

3. Plaintiff KBI-E Inc. ("KBI-E") is a Delaware corporation having its principal place of business at Wilmington, Delaware.

4. KBI-E has exclusive rights in the United States to market and sell products covered by United States Patent Nos. 5,714,504 (the "'504 patent"); 6,369,085 (the "'085 patent"); 6,875,872 (the "'872 patent"); 7,411,070 (the "'070 patent"); and 7,745,466 ("the '466 patent").

5. Plaintiff Pozen Inc. ("Pozen") is a corporation operating and existing under the laws of the State of Delaware, with its principal place of business at 1414 Raleigh Road, Chapel Hill, North Carolina 27517.

6. Upon information and belief, Defendant Watson Laboratories, Inc. – Florida ("Watson Laboratories") was formerly known as Andrx Pharmaceuticals, Inc. ("Andrx Pharmaceuticals"). Upon information and belief, Watson Laboratories is a corporation organized and existing under the laws of Florida, having its principal place of business at 4955 Orange Drive, Davie, Florida 33314. Upon information and belief, Watson Laboratories is in the business of, *inter alia*, developing, manufacturing, and obtaining regulatory approval of generic copies of branded pharmaceutical products throughout the United States, including within this district.

7. Upon information and belief, Defendant Actavis Pharma, Inc. ("Actavis Pharma"), formerly known as Watson Pharma, Inc. ("Watson Pharma"), is a corporation organized and existing under the laws of Delaware, having its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. Upon information and belief, Actavis Pharma is in the business of, *inter alia*, selling and distributing generic copies of branded pharmaceutical products in New Jersey and throughout the United States, including some that are manufactured by Watson Laboratories and/or for which Watson Laboratories is the named applicant of the approved ANDAs.

8. Upon information and belief, Actavis, Inc. ("Actavis") was formerly known as Watson Pharmaceuticals, Inc. ("Watson Pharmaceuticals") until on or around January 24, 2013. Actavis is a corporation organized and existing under the laws of Nevada, having its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. Upon information and belief, Actavis is in the business of, *inter alia*, developing, manufacturing, obtaining regulatory approval, marketing, selling, and distributing generic copies of branded pharmaceutical products throughout the United States, including

within this district, through its own actions and through the actions of its agents and subsidiaries, including at least Watson Laboratories and Actavis Pharma.

9. Upon information and belief, Watson Pharmaceuticals acquired Andrx Pharmaceuticals on or around November 3, 2006. Upon information and belief, Watson Pharmaceuticals renamed Andrx Pharmaceuticals as Watson Laboratories.

10. Upon information and belief, Watson Laboratories is a wholly-owned subsidiary of Andrx Corporation, a Delaware corporation, having its principal place of business at 4955 Orange Drive, Davie, Florida 33314, that is a wholly-owned subsidiary of Actavis.

11. Upon information and belief, Actavis Pharma, formerly known as Watson Pharma, is another wholly-owned subsidiary of Actavis.

12. Upon information and belief, Actavis organizes its operations by divisions— including at least Generics, Brands, and Distribution—and, before the name change, Watson Pharmaceuticals reported its financial results in its Securities and Exchange Commission ("SEC") filings by reference to these divisions. Upon information and belief, Watson Pharmaceuticals consolidated its financial results with subsidiaries in its SEC filings at least since 2007 and did not file separate financial reports to the SEC for each subsidiary.

13. Upon information and belief, Actavis Pharma and Watson Laboratories are involved in the development, manufacture, marketing, sale, and distribution of generic pharmaceuticals. Upon information and belief, each Defendant acts as an agent of the other and/or works in concert with each other

14. Upon information and belief, Watson Laboratories submits ANDAs to the FDA and develops and manufactures products. Upon information and belief, the products

are marketed, sold, and distributed throughout the United States, including in New Jersey, by at least Actavis Pharma. Upon information and belief, Watson Laboratories and Actavis Pharma are parties to one or more contractual agreements regarding the distribution of generic pharmaceutical products.

15. Upon information and belief, the Defendants share at least some common employees, officers, and directors.

JURISDICTION AND VENUE

16. This is an action for patent infringement arising under the Patent and Food and Drug laws of the United States, Titles 35 and 21, United States Code. Jurisdiction and venue are based on 28 U.S.C. §§ 1331, 1338(a), 1391(b), 1391(c), 1400(b), 2201, 2202, and 35 U.S.C. § 271.

17. Upon information and belief, Defendants have been and are engaging in activities directed toward infringement of United States Patent No. 8,557,285 (the "'285 patent" or the "patent-in-suit") by, *inter alia*, submitting to the FDA ANDA No. 204470 ("Defendants' ANDA"). Defendants' ANDA seeks the FDA's approval to manufacture, use, or sell commercially their proposed product called "Naproxen/Esomeprazole Magnesium Delayed Release Tablets, 500mg/20 mg" (hereinafter referred to as the "ANDA Product"), containing the active ingredients naproxen and esomeprazole magnesium, prior to the expiration of the patent-in-suit, as a generic version of the VIMOVO® product.

18. In a letter dated March 29, 2013 ("2013 Notice Letter") from Ms. Janet Vaughn, Watson Laboratories' Director of Regulatory Affairs, Watson Laboratories notified Plaintiffs of the filing of Defendants' ANDA and that the ANDA included a

certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV"), with respect to the '504, '085, '872, '070, '907, and '466 patents.

19. Paragraph IV requires certification by the ANDA applicant that the subject patent "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted ...." 21 U.S.C. § 355(j)(2)(B)(iv) requires a Paragraph IV notice to "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)) specify, *inter alia*, that a Paragraph IV notification must include "[a] detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds of supporting the allegation."

20. Upon information and belief, at the time the 2013 Notice Letter was served, Defendants were aware of the statutory provisions and regulations referred to in paragraph 19, above.

21. Defendants' submission of ANDA No. 204470 and service of the 2013 Notice Letter indicates a refusal to change their current course of action.

22. Defendants' Paragraph IV Notice to Plaintiffs states Defendants' intention to seek approval to market a generic copy of Vimovo® prior to expiration of the '504, '085, '872, '907, '070, and '466 patents. The last of these patents to expire is the '907 patent, which expires on February 28, 2023. The first of these patents to expire is the '872 patent, which expires on November 27, 2014.

23. There is now an actual controversy between Defendants and Plaintiffs as to whether Defendants infringe the '285 patent.

24. This Court has personal jurisdiction over Defendants because, *inter alia*, Defendants, upon information and belief, have purposely availed themselves of the benefits and protections of the laws of New Jersey such that they should reasonably anticipate being haled into court here; Defendants have had continuous and systematic contacts with this judicial district, including, upon information and belief, maintaining executive offices in New Jersey and deriving substantial revenues from the sale of pharmaceutical products in New Jersey; and at least Actavis Pharma, upon information and belief, is licensed to do business within New Jersey. Thus, Defendants are subject to general jurisdiction in New Jersey.

25. Upon information and belief, Watson Laboratories has previously purposefully availed itself of the benefits and protections of the U.S. District Court for the District of New Jersey including by, *inter alia,* filing a complaint in *Shionogi Inc. et al. v. Nostrum Labs., Inc. et al.*, C.A. No. 1:12-cv-04402-RBK-JS (D.I. 1), and asserting counterclaims in this Court in *Depomed, Inc. v. Actavis Elizabeth LLC et al.*, C.A. No. 3:12-01358-JAP-TJB (D.I. 47).

26. Upon information and belief, the acts of Watson Laboratories complained of herein were done at the direction of, with the authorization of, and with the cooperation, participation, and assistance of Actavis Pharma and Actavis.

CLAIM FOR RELIEF: '285 PATENT

27. Plaintiffs reallege paragraphs 1-26, above, as if set forth specifically herein.

28. The ’285 patent (copy attached as Exhibit A), entitled “Pharmaceutical Compositions for the Coordinated Delivery of NSAIDs,” was issued on October 15, 2013, to Pozen, Inc., upon assignment from the inventor John R. Plachetka. The ’285 patent claims, *inter alia*, pharmaceutical compositions in unit dosage form comprising esomeprazole and naproxen.

29. Pozen, Inc. has been and still is the owner of the ’285 patent. The ’285 patent will expire on May 31, 2022.

30. AstraZeneca AB is Pozen Inc.’s exclusive licensee under the ’285 patent.

31. The ’285 patent is a patent with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the VIMOVO® drug product.

32. Accordingly, pursuant to 21 U.S.C. § 355(c)(2), Pozen and the AstraZeneca Plaintiffs are submitting patent information for the ’285 patent to the FDA in connection with its NDA No. 022511 for VIMOVO® drug product. The FDA is expected to publish the same in the Orange Book.

33. On information and belief, the making, using, selling, and/or offering for sale in the United States of Defendants pharmaceutical compositions in unit dosage form comprising esomeprazole and naproxen described in Defendants’ ANDA infringes the ’285 patent.

34. Defendants have infringed the ’285 patent under 35 U.S.C. § 271 (e)(2) by filing their ANDA and continuing to seek approval from the FDA to engage in the

commercial manufacture, use, or sale of a drug claimed in this patent, prior to the expiration of the ’285 patent.

35. On information and belief, the ANDA Product contains the pharmaceutical composition patented in the ’285 patent, constitutes a material part of the inventions of the ’285 patent, is especially made or especially adapted for use in an infringement of the ’285 patent, and is not a staple article or commodity of commerce suitable for substantial noninfringing use. Upon information and belief, Defendants are aware that the ANDA Product is so made or so adapted. Upon information and belief, Defendants are aware that the ANDA Product, if approved, will be used in contravention of Plaintiffs’ rights under the ’285 patent.

36. On information and belief, Defendants have previously filed patent certifications in association with its ANDA No. 204470 seeking, *inter alia*, FDA final approval prior to November 27, 2014. The ’285 patent has an expiration date of May 31, 2022. Therefore, on further information and belief, Defendants are currently pursuing FDA final approval of its ANDA No. 204470 prior to the expiration date of the ’285 patent.

37. Pursuant to 21 U.S.C. § 355(j)(2)(A)(vii), Defendants should file a patent certification in their pending ANDA No. 204470 with respect to the ’285 patent, and Defendants must make a Paragraph IV Certification with respect to the ’285 patent if Defendants continue to seek FDA final approval of their ANDA No. 204470 prior to May 31, 2022. On information and belief, Defendants’ above-described activities are continuing and constitute an act of infringement of the ’285 Patent under 35 U.S.C. § 271(e)(2).

38. On information and belief, the manufacture, use, and sale of the ANDA Product infringes the ’285 patent claims.

39. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(a) A judgment declaring that the effective date of any approval of Defendants' ANDA No. 204470, filed under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), for a drug product called "Naproxen/Esomeprazole Magnesium Delayed Release Tablets, 500mg/20mg" be a date not earlier than the later of the expiration date of the patent-in-suit that is infringed and the expiration of any exclusivity relating to such patent to which Plaintiffs are or will become entitled;

(b) A judgment declaring that the'285 patent has been infringed by Defendants, and remains valid and enforceable;

(c) A permanent injunction against any infringement by Defendants, their officers, agents, attorneys, employees, successors, and assigns, and those acting in privity or concert with them, of the'285 patent;

(d) A judgment that Defendants' infringement is willful;

(e) A judgment that Defendants' conduct is exceptional;

(f) An award of attorney fees in this action under 35 U.S.C. § 285;

(g) Costs and expenses in this action; and

(h) Such other relief as this Court may deem just and proper.

Dated: October 23, 2013

Respectfully Submitted,

By: *s/ John E. Flaherty*

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy is the subject of the following actions:

ASTRAZENECA AB et al. v. DR. REDDY'S LABS. INC., et al., C.A. No. 3:11-cv-02317-JAP-DEA (D.N.J.);

ASTRAZENECA AB et al. v. DR. REDDY'S LABS. INC. et al, C.A. No. 3:13-cv-00091-JAP-DEA (D.N.J.);

ASTRAZENECA AB et al. v. LUPIN LTD., et al., C.A. No. 3:11-cv-04275-JAP-DEA (D.N.J.);

ASTRAZENECA AB et al. v. ANCHEN PHARMS., INC., C.A. No. 3:11-cv-06348-JAP-DEA (D.N.J.);

ASTRAZENECA AB et al. v. WATSON LABORATORIES, INC.- FLORIDA, et al., C. A. No. 3:13-cv-03038-JAP-DEA (D.N.J.);

ASTRAZENECA AB et al. v. MYLAN PHARMACEUTICALS et al., C.A. No. 3:13-cv-04022-JAP-DEA (D.N.J.)

ASTRAZENECA AB, et al. v. MYLAN LABORATORIES LTD. et al., C.A. No. 3:12-cv-01378-JAP-TJB (D.N.J.);

ASTRAZENECA AB et al. v. WATSON LABORATORIES, INC. - FLORIDA et al., C.A. No. 3:13-cv-01669-JAP-TJB (D.N.J.); and

ASTRAZENECA AB et al. v. WOCKHARDT LIMITED et al., C.A. No. 3:13-cv-04854-JAP-TJB (D.N.J.)

The foregoing cases involve products that contain an esomeprazole magnesium formulation. The matter in controversy involves the same esomeprazole magnesium formulations. All of these cases have been assigned to Hon. Joel A. Pisano, U.S.D.J. The DRL, Lupin, and Anchen cases have been consolidated for discovery purposes and have been assigned to Magistrate Judge Arpert.

Therefore, for the sake of judicial economy and with regard to Judge Pisano's and Judge Arpert's familiarity of the patents asserted in the matter in controversy, Plaintiffs believe these

cases and the matter in controversy are all related. Accordingly, Plaintiffs respectfully request that the matter in controversy be assigned to Judge Pisano and Magistrate Judge Arpert.

Dated: October 23, 2013

Respectfully Submitted,

By: *s/ John E. Flaherty*

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